EXHIBIT B

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October 3, 2019

VIA EMAIL
SAGoldberg@duanemorris.com
Seth A. Goldberg, Esq.
Duane Morris LLP
30 South 17th Street
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RE: ***In re Valsartan Products Liability Litigation,*** **No. 1:19-md-02875**
Core Discovery Deficiencies

Dear Mr. Goldberg:

I am writing in advance of the October 7, 2019 meet and confer which is scheduled to take place at your Philadelphia office from 10:00 a.m. to 3:00 p.m. You asked us to provide guidance as to the information we will be seeking. Without prejudice, Plaintiffs expect to address the following issues.

Organizational Structure

1. As stated in prior correspondence, to make the upcoming in-person meeting productive and to enable us to narrow our discovery requests, each Defendant should provide corporate organization charts or similar documents (e.g., corporate directories) in advance of the meeting so that we understand the organization and nomenclature of the various departments within the company, the identities of the employees who worked in each department, as well as the organization of various companies within a corporate umbrella (for example the ZHP umbrella which includes Solco and Prinston), including any changes over time.

2. Plaintiffs need to understand how the various departments within the company interrelate, including division of responsibilities in general, as well as in the context of the

contamination issues in this litigation. For example, Plaintiffs will be asking questions to accurately ascertain the correct custodians and search terms regarding manufacturing, production (including materials sourcing as well as manufacturing), quality assurance, quality engineering, risk management, research and development to the extent relevant to a particular defendant, regulatory, medical affairs, clinical affairs (particular emphasis on identification of those who have evaluated the health risks related to the manufacturing process, both before and after the contamination was disclosed/learned by the public), identification of the departments and employees involved in assessing the contamination, including the amount of contamination, those who are responsible within each company to identify the lots/batches/other quantifications of pills that have been determined to have likely been contaminated, to explain the processes and internal protocols utilized to perform that analysis, the persons responsible for investigating the root cause of the contamination, and the departments and employees who can provide relevant information regarding the economic issues in this litigation, for example market share, number of users, price, cost, value, downstream contract negotiations, and marketability.

Custodians

As a threshold matter, Plaintiffs are in receipt of the proposed custodian lists from ZHP, Mylan, Torrent, Teva and Aurobindo. To date, Hetero USA has not served Plaintiffs with a list of custodians, despite the fact that Defendants told the Court in their letter that all Defendants had provided the required information. Plaintiffs hereby request that Hetero USA serve a list of custodians, as was required under CMO 12, prior to the meeting on Monday October 7, 2019.

Furthermore, the custodian lists provided by Defendants do not denote which years those custodians held the specific roles identified in the lists. The custodian lists also do not provide any temporal context for these custodians. In fact, it appears as though some of the custodians identified by Defendants joined the company in 2018 or 2019. Plaintiffs therefore ask that Defendants identify i) the years the custodians have been with the company, ii) the year or years the custodians have maintained the role identified in the custodian list, and what other roles those custodians have had with the company beyond the identified job position, and iii) all successors or predecessors who held the same roles, job positions, or responsibilities as the custodians listed.

In addition to the above, Plaintiffs also request[1]:

3. Identification of the employees within each Defendant company who have had the primary responsibility to assess the contamination issue, whether from a testing, regulatory, investigation, marketing, or other standpoint.

4. Identification of the employees who were involved in and made the decisions with regard to any changes to the manufacturing process which may be relevant to the claims herein,

[1] Plaintiffs require information for both the United States entities and entities overseas, including but not limited to China and India.

including but not limited to decisions made with regard to the use of solvents in the manufacturing process.

5. Identification of the employees who would be most knowledgeable regarding testing, including testing that was performed before the public dissemination of the contamination issue, which testing may have identified impurities that signaled the contamination that was later disclosed.

6. Identification of the employees and/or other persons/entities who were responsible for investigating and determining the root cause or causes of the contamination.

7. Identification of any employees who were involved in determining what disclosures or messages would be provided to any regulatory agencies, other companies, and to the public.

8. Identification of those employees who may have decided or had input into the decision to not disclose information which may have led to the revelation of the contamination, before the public disclosure that ultimately occurred.

9. Identification of the employees at the overseas facilities, especially in China and India, who will have information with regard to all relevant issues, and their language fluency. This is especially important in the context of discussing translation needs. In order to adequately plan for forthcoming discovery, Plaintiffs must know to what extent important documents will be written in foreign languages, and, more critically, whether certain employees speak in any specific regional dialects that will require more specialized translation.

10. With regard to finished dose manufacturers, and distributors, identification of those responsible for or involved in testing the API, reviewing data and information from the API manufacturers, and communicating with the API manufacturers, including all persons responsible for requesting and soliciting bids from competing API manufacturers.

Regulatory Agents and/or Third Parties[2]

11. Identification of all FDA, EMA, Health Canada, and other relevant regulatory agency liaisons and/or agents contracted by Defendants to communicate with those agencies, in order to determine what role the company played, the contractual relationship, the relevant persons who worked there and interfaced with regulatory agencies, as well as key custodians (discussed above) at the parent company who interfaced with these agents.

[2] Plaintiffs also need to know to what extent these third parties include facilities overseas and where relevant information may be found. As such, Plaintiffs must know the key persons at these affiliates and/or third parties who can be questioned, if necessary, as to the Defendants' access to documents and information that may be held by affiliates in other countries.

12. Identification of all third parties that may have supplied equipment, materials, raw ingredients, or process based services used in manufacturing of Valsartan Containing Drugs ("VCDs"), including the location of these companies, and the years in which Defendants utilized these entities for their VCD manufacturing.

13. Identification of all third parties and/or independent laboratories that conducted independent testing for Defendants, including but not limited to all testing conducted prior to submissions to the FDA of amendments to ANDAs and/or DMFs, all testing regarding manufacturing process changes, and all testing conducted as a result of the FDA recall of the VCDs.

Economic Loss Claims Discovery

Defendants did not provide any names of persons who would have relevant knowledge pertaining specifically to the economic loss consumer and Third Party Payor ("TPPs") suits. The presence of economic loss claims is one fundamental way in which this MDL deviates from Benicar, and will require a more tailored scope of discovery. Additionally, the relevant persons and/or relevant departments pertinent to the economic loss cases cannot be readily discerned from the core discovery produced to date. As such, Plaintiffs request information from Defendants regarding the following:

14. Identification of the relevant departments and/or custodians within Defendants' corporate structure responsible for the following functions related to the sale and distribution of the Defendants VCDs from the date of the submission of its first VCD ANDA or DMF application to present:

a. wholesale pricing, including the wholesale acquisition costs;
b. retail pricing;
c. financial modeling
d. financial forecasting;
e. supply contracts;
f. shelf stock adjustments;
g. distribution services;
h. marketing;
i. contact and contracting with wholesalers;
j. contact and contracting with chain pharmacies;
k. contact and contracting with PBMs; and
l. contact and contracting with TPPs.

15. Identification of all third-party proprietary data sources purchased and maintained by Defendants' detailing the sales and pricing of generic pricing, such as but not limited to, IMS National Prescription Audit data, IMS National Sales Perspective Data, CMS national Health Expenditures data, or Verispan Vector One National data.

Availability of Custodial and Non-Custodial Sources and Documents from Predecessor Entities

On April 8, 2019 Plaintiffs identified a number of issues regarding non-custodial sources, and the ability to retrieve custodial documents. Defendants have never responded to the issues raised in that letter, which still need to be addressed. In particular, for purposes of Monday's meeting, Plaintiffs need to understand:

16. The sources of custodial documents (including both ESI and non-ESI documents) for each defendant and the dates for which such documents are readily available, are available but archived/off-line, and the dates for which they are no longer available and why.

17. The centralized and/or non-custodial sources of information, and the dates of availability of that information.

Beyond those previously identified issues, Plaintiffs also request clarification on the following as it relates to document retention:

18. Plaintiffs note that several entities who independently filed an ANDA or DMF application for a VCD have been bought, merged or otherwise acquired between the years 2010 to present. As such. Plaintiffs request information about whether Defendants have access to documents (including hard copy documents, emails, or other types of electronically stored data) for the following corporations, whether this data is located in an archive, and the necessary steps required to restore this data for custodial productions.

a. Matrix Laboratories;
b. Ivax Pharmaceuticals;
c. Cobalt Pharmaceuticals;
d. Forrest Laboratories;
e. Arrow Pharmaceuticals; and
f. Watson Laboratories.

19. To the extent any potential custodians worked for one of these predecessor entities prior to working for Defendants, Plaintiffs seek information as to whether those persons emails and/or documents from the predecessor entity were maintained and/or archived after the corporate acquisition.

20. To the extent any potential custodians who worked for one of these predecessor entities ceased working Defendants after the acquisition, Plaintiffs seek information as to whether those employees' custodial documents were retained, archived or destroyed.

Search Terms

Plaintiffs proposed a list of search terms to Defendants on September 16, 2019, and have not received any counter-proposals from Defendants as of today. As such, Plaintiffs request Defendants be prepared to discuss the search terms generally. Some specific search term related issues which the parties must discuss include:

21. The terminology and nomenclature used internally by each Defendant with regard to all relevant issues, to help identify correct search terms. In particular, exemplar documents from both US and foreign entities regarding the relevant issues would be very helpful in determining which search terms to use.

22. The searching capabilities and nomenclature of Defendants' document production vendor (e.g., the types of wildcards and search string parameters they can utilize; the ability to do multiple levels of modifiers, any implementation of TAR defendants intend to use).

Very truly yours,

ADAM M. SLATER